REMARKS/ARGUMENTS

Claims 1-2, 4-10 and 12 currently appear in this application. The Office Action of March 20, 2003, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Entry of the present amendment is respectfully requested, as the claims have now been limited to what the Examiner states the specification enables, and now new issues are raised thereby.

The Examiner has maintained the rejection of claims 1-12 under 35 U.S.C. 112, first paragraph, on the grounds that the specification enables a method for determining the level of glucose and hemoglobin in a sample obtained from a hair follicle, saliva, or urine

The present amendment limits the claims to determining the level of glucose from a sample obtained from a hair follicle or urine. Applicant, however, reserves the right to submit claims directed to other samples and other analytes in a divisional application.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete by omitting

essential steps. The Examiner alleges that the claims fail to specifically state what measurement techniques are employed.

This rejection is respectfully traversed. One skilled in the art is well aware of the many types of methods that can be used to determine glucose and hemoglobin. The specification on page 7, lines 11-19, describes some of the most commonly used tests to determine glucose. These tests include fluorescence, chemiluminescense, or bioluminescence methods. One skilled in the art would be familiar with these methods and would choose one suitable for that particular occasion. There is no need to spell out which detection method should be used, since the present invention is not directed to a specific method for determining glucose *per se*, but to a method for detecting glucose in non-blood samples.

As the Examiner is well aware, to conform to the requirements of 35 U.S.C. 112, second paragraph, the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The requirement is that the scope of the claim be clear to a hypothetical person possessing the ordinary level of skill in the pertinent art (see MPEM Section 2171). In the present case, one of

ordinary skill in the pertinent art is well aware of the many types of glucose determinations that are available. Thus, there is no need to recite all of the glucose detection methods in the claim, as the present invention is directed to methods for detecting glucose in a non-blood sample. The steps required in the present invention are:

1. obtain a non-blood sample of hair or urine;
2. determine the volume of blood in the sample by measuring the level of a blood component in the sample;
3. determining either the amount of glucose in the sample or the blood cells present in the sample; and
4. calculating the level of glucose in the blood based on the measurements obtained in steps 2 and 3.

It should be noted that the specification at page 6, line 18 through page 7, line 5, describes a variety of methods for testing for the volume of blood in the sample. Again, the method by which the volume of blood is determined is irrelevant to the present invention; what is important is that the volume of the blood is measured.

With respect to claims 6-12, it should be noted that these claims are claims to a kit, not to a method. Claims 6-12 call for a means for measuring the level of a blood component in the sample as well as means for

calculating the level of glucose in the sample. As noted above, one skilled in the art can readily determine what means are to be used, as detection of blood and glucose in a sample are well known types of determinations. Because there are a great many means for detecting blood and glucose known to those skilled in the art, and the present invention does not depend upon which one of these means is used, it is not necessary and, indeed, is unduly limiting, to recite specific detection methods.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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